

U.S. Serial No.: 10/021,809
Filed: October 30, 2001
Group Art Unit: 3731
Examiner: Uyen T. Ho
Atty. Docket No.: 101896-276 (DEP-5241)

REMARKS

The pending Office Action address and rejects claims 21-24 and 30. Reconsideration is respectfully requested in view of the amendments and remarks submitted herewith.

Amendments to the Claims

Per the Examiner's request, Applicant amends claim 24 to depend from claim 21 and to recite that the lateral passageway is sized to pass a spinal rod therethrough. No new matter is added.

Rejections under 35 U.S.C. §112

The Examiner rejects claim 24 under 35 U.S.C. §112, second paragraph as being indefinite. In particular, the Examiner argues that it is not clear whether Applicant intends to claim an apparatus including a spinal rod or just a cannula. While Applicant disagrees with the Examiner's rejection, Applicant amends claim 24 to recite that the lateral passageway is sized to pass a spinal rod therethrough, thereby obviating the basis for this rejection.

Rejections under 35 U.S.C. §102(b)

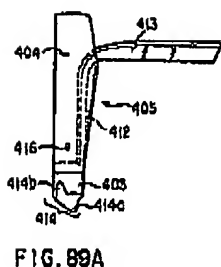
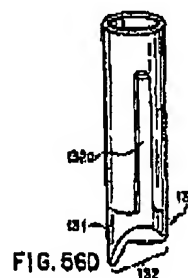
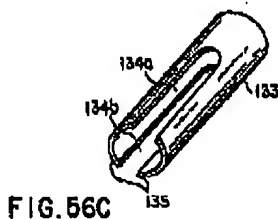
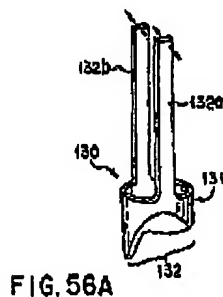
The Examiner rejects claims 21-24 and 30 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,976,146 of Ogawa et al. In particular, the Examiner argues that FIGS. 56D and 97A disclose each and every element of Applicant's claims. Applicant respectfully disagrees.

Independent claims 21 and 30 recite a cannula (claim 21) or a dilator (claim 30) having a distal end with a sloped configuration such that the cannula or dilator has a short side and a long side, and having opposed cut-outs formed in the distal end between the short side and the long side. This configuration allows the distal end to be positioned against a sloped surface of the vertebra, and tools or implants to be inserted through the cut-outs.

Ogawa does not teach or even suggest a device having a distal end configured as required by independent claims 21 and 30. The Examiner relies on FIG. 56D, which is reproduced herein, to illustrate a cannula or dilator having a sloped distal end with two opposed cut-outs formed therein

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between the short side and the long side. This is incorrect. FIG. 56D illustrates a two piece device having a pusher (133) and a cavity securing tool (130), which are shown separately in FIGS. 56A and 56C, which are also reproduced herein. As shown in FIG. 56C, the pusher (133) has opposed cut-out portions formed therein, however it does not have a sloped distal end. Rather, the distal end is straight. The cavity securing tool (130), which is shown in FIG. 56A reproduced herein, similarly does not have a sloped distal end, but rather it has an engagement feature formed thereon for engaging a vertebra. Even if the distal end could be considered to be sloped, the cavity securing tool (130) does not include opposed cut-out portions formed therein. Rather, it includes opposed arms (only one arm 132a is shown) that extend into the opposed cut-out portions in the pusher (133) when the two components are mated to one another, as shown in FIG. 56D. Thus, neither component includes a sloped distal end and opposed cut-out portions as required by claims 21 and 30. Ogawa also fails to disclose cut-out portions positioned between a short side and a long side of a sloped distal end, as is further required by claims 21 and 30.



The embodiment shown in FIG. 97A of Ogawa also fails to teach or even suggest a cannula or distractor having opposed cut-outs formed in a sloped distal end between a short side and the long side, as required by independent claims 21 and 30. Rather, as shown in FIG. 89A, which is reproduced herein and represents a view of the device used in FIG. 97A, the device has a distal end with an engagement feature adapted to rest against a vertebra, and only one cut-out 414b located at its distal end.

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Accordingly, claims 21 and 30 distinguish over Ogawa and represent allowable subject matter. Claims 22-24 are allowable at least because they depend from an allowable base claim.

Rejections under 35 U.S.C. §103(a)

The Examiner also rejects claims 21-24 and 30 pursuant to 35 U.S.C. §103(a) as being obvious over Ogawa. The Examiner argues that Ogawa discloses in FIGS. 75B, 75C, and 76B a cannula having opposed cut-outs formed in the distal end and defining a lateral passageway oriented at an angle to a working channel. However, the Examiner admits that the embodiments shown in FIGS. 75B, 75C, and 76B does not teach a sloped distal end. Thus, the Examiner relies on FIGS. 63A, 100A, 121, and 132 to teach a cannula having a sloped distal end, arguing that it would have been obvious to modify the embodiment shown in FIGS. 75B, 75C, and 76B to include a sloped distal end "in order to provide a distal end having a contour that fit [sic] the surgical site." Applicant respectfully disagrees.

The Examiner has failed to establish a prima facie case of obviousness for several reasons. At the outset, the combination of features in Ogawa does not teach the claimed invention. The Examiner has further failed to identify the motivation necessary to combine the features, and rather is improperly relying on hindsight to pick and choose among isolated features in the prior art to piece together the claimed invention.

1. The Combination Of Features in Ogawa Does Not Teach The Present Invention

The Examiner has failed to recognize that Ogawa does not teach or even suggest a cannula having opposed cut-outs that are positioned *between a short side and a long side* of a sloped distal end. The embodiments shown in FIGS. 75B, 75C, and 76B merely teach opposed cut-outs formed in a guide device having a straight end, and the embodiments shown in FIGS. 63A, 100A, 121, and 132 merely teach a cavity securing tool or sheath having a curved or shaped end with no cut-outs. None Ogawa does not teach or even suggest positioning the cut-outs in FIGS. 75B, 75C, and 76B between a short side and a long side of the shaped distal end of the embodiments shown in FIGS. 63A, 100A,

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121, and 132. Accordingly, even if the various features of the embodiments disclosed in Ogawa were combined, the combination would not result in the claimed invention.

2. *The Examiner Has Failed To Identify A Motivation To Combine The Features of Ogawa, And Rather Is Improperly Relying On Hindsight*

The Examiner fails to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. In combining references to support an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The teaching or motivation must come from the references, and it cannot be derived from Applicant's teachings.

In the pending Office Action, the Examiner concludes that a person having ordinary skill in the art would be motivated to modify the guide device with cut-outs shown in FIGS. 75B, 75C, and 76B to have a shaped distal end as shown in FIGS. 63A, 100A, 121, and 132 to "provide a distal end having a contour that fit[s] the surgical site." The Examiner's argument is flawed because the guide device shown in FIGS. 75B, 75C, and 76B is merely used "for guiding a port to a target site." (Col. 36, lines 13-14.) Once the flexible port (11), shown in FIG. 15, is positioned around the guide wires (218), the guide port is removed. Accordingly, it does not need to "fit the surgical site," as suggested by the Examiner. Therefore it would not have been obvious to a person having ordinary skill in the art to modify the guide device shown in FIGS. 75B, 75C, and 76B to include a shaped distal end, as shown in FIGS. 63A, 100A, 121, and 132.

The Examiner's obviousness rejection can only be the product of impermissible hindsight. An Examiner may only establish a prima facie case of obviousness when "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). In asserting that the prior art "suggested" the claimed subject matter, however, an Examiner must realize that "the mere fact that the prior art may be modified in the manner proposed by the Examiner neither makes the modification prima facie obvious nor obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[A] rejection cannot be predicated on the mere

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identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Werner Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *Id.* The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Accordingly, claims 21 and 30 distinguish over Ogawa and represent allowable subject matter, and claims 22-24 are allowable at least because they depend from an allowable base claim.

Conclusion

Applicant submits that all claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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